

the [INGAP] polypeptide is involved in islet cell neogenesis.” The specification clearly teaches that the INGAP protein stimulates islet cell neogenesis. See column 7, lines 45-50. Nonetheless, the PTO’s assertion appears to require that the specification teach the biochemical mechanism by which INGAP protein stimulates islet cell neogenesis. The PTO has not asserted any basis in law for such a requirement that a biochemical mechanism of action be taught, and the applicants are not aware of any such requirement. Knowledge of a biochemical mechanism is not necessary to practice the invention or to demonstrate possession of the invention.

The Office Action further asserts that claims 1, 12, and 17 are not adequately described for failing to recite a function of the polypeptide. Claims 1, 12, and 17 are described by sequence. Claim 1 recites a DNA molecule that encodes the amino acid sequence of SEQ ID NO: 2. Claim 12 recites at least 30 contiguous nucleotides of such a DNA molecule. Claim 17 recites a nucleotide sequence which encodes all or a portion of a protein as shown in SEQ ID NO: 2. Because each of these claims recites nucleotide sequences which encode a specific amino acid sequence, and the specific amino acid sequence has been taught to have a particular function (stimulates islet cell neogenesis) they are fully described. There is no constitutional, statutory, regulatory, or policy requirement that mandates that a protein function be recited for such claims. The PTO has failed to supply any reasoning to support such a requirement.

Claims 17 and 24 are singled out as reading on portions of INGAP. The set of portions is said to be a large and variable genus. Claim 17 is directed to portions of the INGAP coding sequence which are useful in antisense constructs and claim 24 is directed to portions which are useful as nucleic acid probes. These claimed subject matters are not dependent on the polypeptide function of INGAP for their functionality. Portions of the coding sequence are acceptably functional for both antisense and probes. In both cases the functionality depends on the ability of a nucleotide sequence to hybridize to a complementary nucleotide sequence. It is not material if the portion does not encode a complete or functional INGAP polypeptide.

Claim 19 is singled out as directed to a fragment of the nucleotide sequence which may not encode the full INGAP protein. However, the PTO has misconstrued claim 19. Claim 19 is dependent on claim 1. Claim 1 specifies that the DNA molecule encodes an INGAP protein having the sequence shown in SEQ ID NO: 2.

Since claim 19 necessarily incorporates all the limitations of claim 1, claim 19 also *must* encode an INGAP protein. The function of the full INGAP protein has been taught in the specification.

The rejection faults the specification for failing to teach other species of INGAP from other sources. However, each of the claims recites the sequences of SEQ ID NOS: 1 and/or 2. Thus description of other unclaimed species of INGAP from other sources should not be required.

Similarly the rejection faults the specification for failing to teach the amount of variation among species within the genus. However, as mentioned above, all claims are based on a single amino acid sequence and a single nucleotide sequence. The size of such a genus is not large.

Withdrawal of this rejection is respectfully requested.

#### **The Rejection of Claims 17 and 24 Under 35 U.S.C. § 251**

Claims 17 and 24 have been rejected under 35 U.S.C. § 251 as improperly attempting to recapture subject matter surrendered in the application for the patent upon which the present reissue is based. Applicants respectfully traverse.

Claim 17 does not improperly recapture subject matter surrendered during prosecution. Claim 17 originally and as amended recited a nucleotide sequence consisting of a mammalian INGAP gene. The amendment during prosecution inserted the sequence of the encoded protein. However, the *size* of the nucleotide sequence recited was not altered. Thus applicants never surrendered subject matter including portions of INGAP, as such subject matter was not originally encompassed within the claim. Having never surrendered such subject matter, applicants cannot now improperly *recapture* such subject matter.

Claim 24 did not exist before. It depends from claim 12 which now recites and originally recited “at least 30 contiguous nucleotides.” Applicants cannot improperly *recapture* subject matter which they never before claimed or surrendered.

#### **The Rejection of Claims 11 and 14 under 35 U.S.C. § 112, Second Paragraph**

Claims 11 and 14 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse.

The Office Action asserts that claims 11 and 14 are indefinite for reciting “detectable moiety” because it is unclear to what “detectable moiety” the claims refer. The standard for assessing whether a patent claim is sufficiently definite to satisfy the statutory requirement is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870 (Fed. Cir. 1993).

Applicants had previously pointed to the specification as teaching certain detectable moieties, such as radiolabels, fluorescent labels, enzymes, etc.” The final rejection did not find that convincing because limitations from the specification cannot be read into the claims. Applicants fully agree and did not intend that the term detectable moiety should be limited to the labels disclosed. Applicants intended that the list would illuminate and exemplify the term “detectable moiety.” Applicants found that 124 issued U.S. patents have used this term in the last 5.75 years. List appended. The term thus appears to be a term of art that those of skill in the art understand.

Withdrawal of this rejection is requested. If the rejection is maintained applicants request that the PTO explain what is unclear about the term.

#### **Provisional Double Patenting Rejection of Claims 1-24**

Claims 1-24 are provisionally rejected as unpatentable over claims 1-49 of co-pending Application No. 09/659,379. Applicants respectfully traverse.

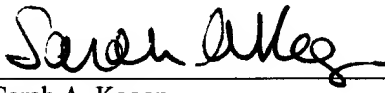
The claims of the ‘379 application are not an obvious variation of the claims of the subject application. The ‘379 application requires that the signal sequence be absent in nucleic acid constructs. This is not taught or suggested by the subject claims. The subject claims recite the full coding sequence including the signal sequence. It would not have been obvious to make the constructs lacking the signal sequence based on the full sequence. Thus the claims are patentably distinct.

Withdrawal of the double patenting rejection of claims 1-24 is respectfully requested.

**Request for Interview**

Please contact the undersigned by telephone to arrange a convenient time for a personal interview.

Respectfully submitted,

By:   
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